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Separate paging is given to this Part in order that it may be filed as a Separate Compilation.

PART IV-B

Rules and Orders (Other than those published in Parts I, I-A, and I-L) made by the Government of Gujarat under the Gujarat Acts

HEALTH AND FAMILY WELFARE DEPARTMENT NOTIFICATION

Sachivalaya, Gandhinagar, 16th December, 2023

GUJARAT CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2021.

No.GHY-22-2023-GCA-102021-1314-A.- The following draft of rules which is proposed to be issued under sub-section (1) of section 45 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (Guj. 18 of 2021) is published as required by aforesaid section of the said Act, for information of all persons likely to be affected thereby; and notice is hereby given that the said draft rules will be taken into consideration by the State Government on or after the expiry of thirty days from the date of publication of this notification in the *Official Gazette*.

2. Any objection or suggestion which may be received by the Principal Secretary to the Government of Gujarat, Health and Family Welfare Department, Block No. 07, Sardar Bhavan, Sachivalaya, Gandhinagar from any person with respect to the said draft of rules before the expiry of the aforesaid period will be considered by the Government.

NOTIFICATION

GUJARAT CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2021.

No.GHY-22-2023-GCA-102021-1314-A.-In exercise of the powers conferred by sub-section (1) of section 45 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (Guj. 18 of 2021), the Government of Gujarat hereby makes the following rules further to amend the Gujarat Clinical Establishments (Registration and Regulation) Rules, 2023, namely:-

1. (1) These rules may be called the Gujarat Clinical Establishments (Registration and Regulation) (Amendment) Rules, 2023.
(2) They shall come into force from the date of their publication in the *Official Gazette*.

- 2.** In the Gujarat Clinical Establishments (Registration and Regulation) Rules, 2022 (hereinafter referred to as “the said rules”), in rule 2, in sub-rule (1), after clause (a), the following clauses shall be added, namely
- (b) “Annexure” means annexure appended to these rules;
 - (c) “Blood bank” means a blood bank as defined in the Drugs and Cosmetic Rules, 1945 from time to time;
 - (d) “Clinic or Poly-Clinic” means a place where treatment for illness is offered with or without injection, minor operation, dressing etc. to the patients for only observation and not as in-door patients and may include Endoscopic Clinic, AYUSH Clinic, Dental Clinic or any other establishment offering treatment for illnesses by use of medicines or any therapy under any recognised system of Medicine;
 - (e) “Consulting Room” means a place where consultation, including examination of the patients and issue of prescription is done and medical advice is provided;
 - (f) “Council” means the State Council for Clinical Establishments;
 - (g) “Dental Clinic” means a clinic where treatment for dental ailments is offered with or without injection, minor operation, dressing etc.;
 - (h) “Dental Hospital” means a place where patients are treated as inpatient and treatment is given for dental ailments;
 - (i) “Hospital” means and includes a Nursing Home or Health Centre or Treatment Centre or any other place where facilities for admission as in-patients for treatment of illness with or without surgery or conduct of delivery etc., with or without out-patient facilities and diagnostic facilities like laboratory etc., in any recognised system of medicine;
 - (j) “Laboratory” means a place where bio-medical or bio-chemical or clinical pathology or biopsy or bacteriological or genetic investigations or any diagnostic tests or investigative services are carried out;
 - (k) “Patient” means a person who reports himself or brought to any clinical establishment including newly born child for treatment or consultation or seeking any other services rendered by the such clinical establishments;
 - (l) “Pharmacist” means a person registered under the Gujarat State Pharmacy Council who is professionally qualified to prepare and dispense medicinal drugs as per the government guidelines;
 - (m) “Qualified Nurse” means a person who possess the required qualification from any of the Nursing Teaching Institutions, recognized by the Indian Nursing Council and enrolled with the Gujarat Nursing Council under the Indian Nursing Council Act, 1947 (Central Act XLVIII of 1947).
 - (n) “Registered Medical Practitioner” means a person who possess any of the Government recognised medical qualification and who has been enrolled in the register of the respective Council viz., Medical, Dental, Siddha, Ayurveda, Unani or Homeopathic Councils or the Board of Indian Medicine or any such Council, Board or any other statutory body established or recognised by the Government of Gujarat or Government of India;
- 3.** In the said rules, after rule 8, the following rule shall be inserted, namely:-
- “8A. Minimum facilities of Clinical Establishment. –**
- (1) The floor space and other facilities, the minimum number of staff and their minimum qualification, minimum equipment and other conditions required for a clinical establishment, for providing different medical services including specialized services shall be in accordance with the norms and conditions specified in **Annexure-9**.
 - (2) If, at any time clinical establishment violates the conditions of registration or any of the provisions of the Act or rules made thereunder, the District Authority or the State Council, as the case may be, may take appropriate action under the Act.”.
- 4.** In the said rules, in rule 9, for sub-rule (6), the following sub-rule shall be substituted, namely:—

- (6) In event of change of management or ownership, the clinical establishment shall inform in writing to the District Registering Authority regarding the change of management or ownership or RMP in-charge of Hospital within two months. The clinical establishment shall make an online application on the government portal in Annexure-1A for such changes along with payment of fees specified in Annexure 7.

5. In the said rules, in rule 10, in sub-rule (1), after the words “necessary information filled”, the words “in Annexure-1A” shall be inserted.
6. In the said rules, in rule 12, after the words “provisional certificate”, the words “in Annexure-1A” shall be inserted.
7. In the said rules, after rule 10, following rule shall be added, namely:-

“10 A. Application for obtaining certificate of registration under rules 9 and 10 -

- (1) Every clinical establishment shall make an application under rule 9 and rule 10 as per Annexure-1A. If a clinical establishment is offering services in more than one recognised system of medicine, it shall make separate application for obtaining certificate for each system of medicine;

Provided that a laboratory or a diagnostic center which is a part of a clinical establishment shall not be required to registered separately.

- (2) The clinical establishment shall be required to submit the documents specified in Annexure –1A along with the application for obtaining provisional certificate of registration and permanent certificate of registration.
- (3) The amount collected by way of fees, fines and penalties by the Council and the Authority under section 35 and Section 36 shall be credited to such account as the State Government may, by order specify in this behalf and shall be utilized for the activities connected with the implementation of the provisions of this Act”.
8. In the said rule, after rule 13, following rules shall be inserted, namely:-

“14. Duties of clinical establishment. - Every clinical establishment shall, -

- (a) display a copy of the Certificate of Registration of the clinical establishment in a prominent place of the premises open to public;
- (b) maintain records in electronic form showing the names, addresses and the qualifications of its employees and the equipment maintained by establishment and if any changes to it, report to the authority half yearly;
- (c) display of rates charged by Clinical Establishment;
- (d) maintain clinical records -(i.e any paper, film, printout, slide, solution, medium which can be deciphered or used to indicate and diagnose the condition of the human body or a part of it or any material taken out of it and the course of treatment administered to or undergone by the person), of its activities relating to a patient. The patient shall be given case records containing name, age, gender and date of consultation, diagnosis (either provisional or final) and treatment advised preferably electronically including the laboratory and diagnostic results, and the investigation undertaken shall be entered;
- (e) each record shall be kept open for inspection to the competent authority;
- (f) every clinical establishment shall facilitate to segregate and dispose the waste including biomedical waste as per the applicable norms or guidelines of the Government of India and Gujarat Pollution Control Board;
- (g) surrender of the Certificate of Registration, on ceasing to function as a clinical establishment.
- (h) It shall be the duty of every clinical establishment to provide a list of patients every month who are suffering from Tuberculosis or other notifiable diseases notified under the Epidemic Disease Act,1897 and getting treatment under concerned clinical establishment along with necessary details of communication address,

contact number and other information to local Public Health Authority namely, Chief District Health Officer of a District or Municipal Health Officer of concerned urban local body in whatever way they are known.

15. Maintenance of medical records. – (1) Every clinical establishment shall maintain records with particulars relating to the clinical observation, test, investigation, diagnostic opinion, advice and treatment given to the patient, who has visited the clinical establishment either as an in-patient or out-door patient in Annexure-10.

(2) In the case of unseen events, pandemic or any disasters, the clinical establishments must provide records as required by the Health and Family Welfare Department.

(3) The record of OPD shall be maintained electronically for minimum five years, IPD record shall be maintained for minimum ten years and in case of court-case/medico legal cases/consumer forum cases, the related record shall be maintained till the final disposal of the case.

16. Publication of list of clinical establishments –

(1) The Authority/State Council shall display the list of clinical establishments registered in Gujarat and update the same on online platform every month in Form-A of Annexure-11.

(2) The Authority shall display the list of the clinical establishments whose registration has expired and update the same on online platform in Form-B of Annexure-11.

17. Manner of inspection in case of a clinical establishment -

(1) Entry and inspection or inquiry of the clinical establishment shall be done by the authority/State council/health and family welfare department or team duly authorized by it or subject to such general or special orders as may be made by the authority/ State council /health and family welfare department.

(2) The inspection team shall give notice to the establishment about the visit. In cases where there is a complaint against any establishment, inspection team of Authority can visit to the establishment without giving prior notice.

(3) The team shall examine premises used or proposed to be used for the clinical establishment and inspect the equipments, furniture and other accessories and enquire into the professional qualifications of the technical staff employed or to be employed and may make any such other enquires, as it consider necessary to verify the statements made in the application for registration and grant of license. All persons connected with the running of the establishment shall be bound to provide full and correct information to the inspection team.

(4) The inspection team shall submit a report in Annexure-12 within a week of the inspection to the authority and shall also forward a copy thereof to the State Council.

18. Disobedience of direction, obstruction and refusal of information.

(1) In case of disobedience of direction, obstruction and refusal of information required by any person of authority empowered under the Act, District Registering Authority or Council, shall hold an inquiry after giving the concerned person a reasonable opportunity of being heard for the purpose of imposing penalty.

(2) The person aggrieved by the decision of the Authority may prefer an appeal to the State Council within the period of three months from the date of receipt of such decision.

- (3) State Council or the person authorised by the State Council on receipt of such appeal, if he considers that, an interim order is necessary in the matter, he may pass such an order.
- (4) State Council or the person authorised by the State Council may pass such order as he deems fit after giving a reasonable opportunity of being heard.
- (5) The decision of the appellate authority shall be communicated to the person concerned within fifteen days from the date of passing of such order.
- (6) The decision of the appellate authority shall be final and binding.”

9. In the said rules, for Annexure 7, the following Annexure shall be substituted, namely:-

“Annexure –7

(See rules 9, 10 and 12)

Fees for Application of Registration/ Renewal of Different Clinical Establishment

Sr.	Establishment Type	Fees of application for provisional registration (in Rs)	Fees of application for permanent registration(in Rs)	Fees for appeal against District Authority Order (in Rs)
1	Clinic/consulting room	1000/-	2000/-	1000/-
2	Poly -clinic	2500/-	10000/-	2500/-
3	Establishment up to 30 beds	5000/-	20000/-	5000/-
4	Establishment 31 to 50 beds	10000/-	40000/-	10000/-
5	Establishment 51 to 100 beds	15000/-	75000/-	10000/-
6	Establishment more than 100 beds	50,000/-	200000/-	15000/-
7	Lab/ Other diagnostic unit	5,000/-	20,000/-	3000/-

- For late Application the amount would be double of the Provisional / Permanent registration fee.
- For change of ownership, management or name of establishment would be half the amount of Provisional/ Permanent registration fee.
- For renewal of permanent registration half the amount of the permanent registration fee.
- For obtaining the duplicate certificate the amount would be 10 percent of the amount of Provisional /Permanent registration fee”.

10. In the said rules, after Annexure 1, the following Annexures shall be inserted, namely:-

“Annexure – 1A

(See rule 9, 10A, 12)

Application Form for Permanent Registration/

Renewal of Registration / Change of Management or Ownership of Clinical Establishment

Establishment Details

1. Name of the Clinical Establishment:	1. Registration Number (provisional/ permanent provided by the Authority if available): 2. valid till:	
Type of clinical Establishment (Consulting Room, Clinic, Poly clinic, Hospital ,Dental Clinic, Clinical Laboratory, X-ray Centre and imaging Centre)		
Category of Clinical Establishment (Allopathy, Ayurveda, Siddha, Homeopathy, Yoga, Naturopathy)		
2. Address:		
Village/Town:	Taluka:	
District:	State:	Pin code:
Telephone No.(with STD code)	Mobile:	
Email ID:	Website URL address (if any)	
3. Year of starting:		

4. Ownership of Services. (Fill/ Mark all whichever is applicable)–

Public Sector

Central Government	State Government	Local Government (please specify)
Public Sector Undertaking	Railways	Employees State Insurance Corporation
Grant-in-Aid institutions	Autonomous organization	Society/Not for profit Companies
Any other (please specify)		

Private Sector

Individual Proprietorship	Partnership firm (Including LLP)	Registered Company
Corporation (including a society) registered under a Central, Provincial or State Act (Please specify)		
Trust (including Charitable) registered under a Central, Provincial or State Act (please specify)		
Branch of a Foreign Service provider (please specify)		
Any other (please specify)		

5. Name of the owner(s) of Clinical Establishment:

Name:	Address:	
Village/Town:	Taluka:	
District:	State:	Pincode
Telephone No. (with STD code)	Mobile No.:	Email ID:

6. Name, Designation and Qualification of person-in-charge of the clinical establishment (it could be same as owner)

Designation: Registration No (GMC/IMC):	Qualification:	
Address:		
Village/Town:	Taluka:	
District:	State:	Pin code:
Telephone No.(with STD code):	Mobile:	Email ID:

Any other (please specify):

7. Type of clinical establishment:(Please mark/ tick whichever is applicable)

Clinic

Single Practitioner	Consulting Room	Polyclinic
Dental	Psychiatry	Any other (Please specify)

Centre

Primary Health Centre/Health & Wellness Centre	Community Health Centre	Urban (UHWC/UPHC/UCHC)
Dispensary	Day Care Centre	Counselling centre
Physiotherapy Centre	Drug De-addiction Centre	In Vitro Fertilization (IVF) Centre/ART Clinic/ART Centre/ART Bank
Dialysis	Hospice Centre	Any other (like Audiometry, Prosthetic & orthotic etc., (please specify)

Hospital

General Practice Services	Maternity Home
Single speciality Services	Multi Speciality Services
Super speciality Services	Operation Theatre
Emergency Causality	Intensive Care Unit
ICCU	Drug de-addiction hospital
Psychiatry nursing home/ Hospital	Any other please specify

8. Whether the clinical establishment,-

- (a) is attached with Laboratory (if so, please mark/tick whichever is applicable)

Pathology	Haematology	Histopathology
Cytology	Genetics	Samples Collection Centre
Biochemistry	Microbiology	Any other (please specify)

If answer to (a) above is yes, the following details may be furnished, namely:

- Tests that it proposes to carry out
- List of equipments available
- A list of technical staff (both technical and supervisory)
- List of personnel who are going to sign test reports.

- (b) is attached with X-ray and Imaging Centre (if so, please tick whichever is applicable)

Portable X ray	Conventional X Ray	Digital X Ray
X Ray with computed Radiography system	Ultrasound	Ultra sound with Color Doppler
Mammography	Orthopentogram(OPG)	CT Scan
Magnetic Resonance Imaging (MRI)	Positron Emission Tomography (PET) Scan	Bone Densitometry
Uro-flowmetry	Any other (Please specify):	

- (c) is attached with Blood Banks (if so, please tick whichever is applicable)

- (A) Based on Location

Stand alone	Hospital Based	Any other (please specify)
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- (B) Based on Facilities(please specify):

Blood bank having whole blood facility only
Blood bank/having whole blood and component facility
Blood bank having whole blood and/or component facility with any other additional facility

9. List of the equipments:-**10. System of Medicine: Services offered (please tick whichever is applicable)**

- (a) Allopathic Speciality

Medical and Allied	Surgical and Allied	Obstetrics and Gynecology	Any other please specify
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- (b) Ayurveda

Anusadh Chikitsa	Shalya Chikitsa	Shodhan Chikitsa	Rasayana
Pathya Vyavastha	Any other please specify:		

(c) Unani

Matab	Jarahat	Ilaj-bit-Tadbeer	Hifzan-e-Sehat
Any other please specify			

(d) Siddha

Maruthuvam	Sirappu Maruthuvam	Varmam Thokknam & Yoga
Any other please specify		

(e) Homeopathy

General Homeopathy	Any other please specify
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(f) Naturopathy

External Therapies with natural modalities	Internal Therapies
Any other please specify	

(g) Yoga

Ashtang Yoga	Any other please specify
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11. Area of the establishment (in square metres)

(a) Total area: _____ (b) Constructed Area: _____

12. Out-Patient Department

Total number of Out Patient Department Clinics

Sr. No.	Speciality	Number of Rooms

13. In-Patient Department

- (a) Total number of beds:
(b) Specialty-wise distribution of beds, please specify:

Sr.No.	Speciality	Number of beds

14. Biomedical Waste Management

- (a) Method of treatment and/or disposal of bio-medical waste:
i. Through Common Facility
ii. Onsite Facility
iii. Any other (please specify)
- (b) Whether authorization from Pollution Control Board obtained?

Yes No Applied for

15. Total number of Staff (as on date of application):

Number of permanent staff: Number of temporary staff:

(A)

Category of Staff	Name	Qualification	Registration Number	Nature of Service Temporary/Permanent
Doctors				
Nursing Staff				
Para-medical Staff				
Pharmacists				

(B) i. Number of Support Staff:

- ii. Number of Administrative Staff:
- iii. Others, Please specify

16. Clinical establishment shall upload following certificates as applicable:

- a) BU certificate as given by local/ competent authority
- b) NOC for Fire safety by competent authority
- c) GPCB biomedical waste management certificate
- d) Authorization from Atomic Energy Regulation Board (Radiology)
- e) Drug and Cosmetic Act-1985 certificate
- f) Authorization under PC&PNDT Act-1994
- g) Certificate of registration under Assisted Reproductive Technology (Regulation Act, 2021)
- h) Certificate of registration under surrogacy (regulation) Act 2021,
- i) License for blood bank or authorization for blood storage facility
- j) Reasonable numbers Photographs (restricted to five) of Clinical Establishment

17. Payment options for Registration Fees:

Payment option (tick any): Online Transaction

Online Transaction Id.:

Amount (in Rs.):

Date:

Details:

I / We hereby declare that the statement stated above are true and correct to the best of my/our knowledge and I/We shall abide by the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 and the Rules made thereunder.

I fully understand that in case any of the submitted documents are found to be false or if it is found that I have not fulfilled any of the provisions of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 and the Rules, the Competent Authority shall be at liberty to penalize me / cancel registration as per the provisions of the Act.

Place:

Date:

Signature of the Authorized person of the clinical establishment

Acknowledgment

Received Application for Registration from.....

Signature of CDMO/CDHO/superintendent

Name:

Date with Seal:

11. In the said rules, after Annexure 8, the following Annexures shall be added, namely:-

“Annexure-9
(See rule 8A)

A. Allopathy System

I. Consulting Room. -

- (1) **Infrastructure.** - Consulting room shall have sufficient space with light and ventilation. Separate space for the patients waiting for consultation has to be provided.
- (2) **Staff.** - The examination of the patient and prescription of the treatment shall be done only by a registered medical practitioner as required under the Indian Medical Council Act / National Medical Commission Act as applicable.
- (3) **Equipment.** – The equipments and hospital accessories shall be available in the consulting room according to concerned speciality.
- (4) **Prescription slip.** - The RMP shall sign the prescription slip with date and registration number with concern council and ABHA as agreed to by patient.

II. Clinic. - In addition to the norms prescribed for a consulting room, the following norms are required to be fulfilled, namely: -

- (1) **Building.** - Sufficient space shall be available for keeping the patient under observation in case of anaphylaxis or for giving intravenous drip or for observation etc.,
- (2) **Staff.** - Minimum of a Registered Medical Practitioner (RMP) and a qualified paramedical staff.
- (3) **Equipments.** –clinic should have all necessary equipments as per service provided.
- (4) **Waste Disposal.** - Facilities to segregate and dispose the waste including Biomedical waste as per the Government of India and Gujarat Pollution Control Board norms.
- (5) **Dispensation of Medicine.** - If the clinic is also engaged in dispensing medicines to the patients, the same shall be done only by a qualified pharmacist or by the Registered Medical Practitioner (RMP) of the clinic or under his direct supervision.
- (6) **Laboratory in a Clinic.** - If the clinic is providing laboratory services, the laboratory work shall be supervise and approved by a qualified person specified in Annexure-9.
- (7) **X-ray (radiograph).** - If the clinic is having its own X-ray unit, the X-rays shall be taken by a qualified radiographer recognized by the Government as per Allied Healthcare Professional Council.
- (8) **Minor Surgeries.** - In case of minor surgeries or minor surgical procedures like cyst excision, Medical Termination of Pregnancy (MTP), Dilatation and Curettage (D&C) are under taken it is advisable to have a sterile room for the purpose and facilities available as given for minor Operation Theatre.

III. Polyclinic. - (1) In addition to the norms prescribed for clinic and consulting room, separate cubicles/rooms/spaces shall be made available for each specialties, if they are being attended simultaneously.

- (2) Reasonable space for waiting room and provision of safe drinking water and toilet shall be made available for the patients. Names of different Registered Medical Practitioner (RMP) attending shall be exhibited in the waiting room.

IV. Hospital. –

(1) **Infrastructure.** - In addition to the norms prescribed for Clinic, Consulting room and Polyclinic, the waiting room shall be made available for the patients/those accompanying them, which shall have sufficient space

(2) **Ward or in-patient room clusters. –**

(a) **Space-**

- (i) Ward or in-patient room shall be spacious with good ventilation and light. Electric fan shall be provided to each room and one fan for at least two beds shall be provided for common rooms.
- (ii) Toilets may be common or separate, but shall be clean and provided with water.
- (iii) Cleaning arrangements shall be made to swab the wards daily with antiseptic liquid.

(b) **Staff.**

- One Qualified RMP for every thirty beds
- One RMP shall be on call duty up to thirty beds during night and off duty hours.
- On duty RMP shall be available in the hospital physically for every thirty beds and above in general side for all the 24 hours.
- If the hospital is having less than thirty beds, but if an Intensive Care Unit (ICU) is functioning, one RMP per ten beds shall be available on duty for 24 hours .
- (ii) **Nurses.** Three qualified nurse shall be available round the clock for up to thirty beds in a clinical establishment and then for each additional ten beds one qualified nurse shall be available.
The aforesaid human resource is the minimum requirement irrespective of the fact the availability of any number of trained personnel working in the hospital.
- (iii) **Attendant** - Male and female attendants shall be engaged in sufficient number depending on the bed strength to assist the RMPs and nurses in their duties like dressings, enema and preparation of patients for surgery, delivery etc. but they shall not be given the task of giving injections or doing suturing etc. They shall work under the nurse.
- (iv) **Cleaning Services.** - Sufficient number of cleaning personnel (sweeper/sanitary worker) shall be available in the clinical establishment. At least one sweeper/sanitary worker available round the clock per thirty beds is the minimum requirement.

(3) **Other Services. -**

(a) **Pharmacy.** - If a pharmacy is maintained in the hospital for dispensing medicines to the patients, it shall be done by a registered qualified pharmacist only and he should not prescribe any drugs.

(b) **Laboratory. –**

If the hospital is providing laboratory services, the laboratory work shall be supervise and approved by a qualified person specified in Annexure-9.

(c) **X-Ray (Radiograph).** - X-Ray department shall confirm to the norms prescribed in part-VIII of this Annexure.

(d) **Blood Bank.** - If a blood bank is maintained by a hospital, it shall confirm to the standards/requirements prescribed by the Government of India (i.e. Drugs and cosmetic Act 1940) from time to time.

(e) **Ambulance.** - It is desirable that, all Hospitals having more than fifty beds shall have an Ambulance with a driver available or alternatively they shall have tie up arrangement with another Hospital having Ambulance or some Ambulance service unit.

(f) **Catering and Canteen.** - If catering arrangements are available, the Kitchen shall be clean and the cooks shall be periodically medically examined. FSSAI standards shall be followed as issued by time to time. Clean practices shall be maintained in the canteen and kitchen.

(g) **General facilities. -**

- (i) **Bio-medical Waste disposal.** – Bio-medical Waste disposal shall be as per the Government of India norms and Guidelines issued by Government of India or Gujarat Pollution Control Board. Proper segregation of the waste at the point is to be ensured.

(ii) Record Keeping. –

All medical record should be maintained as per the code of medical ethics regulation 2002 published by National Medical commission and amended time to time.

- (4) Mortuary room.** - A hospital having more than fifty beds shall have a mortuary room or room with freezer box facilities for the dead bodies.
- (5) Water Supply.** - Potable water supply shall be made available. Hot water supply also to be provided.
- (6) Clothing and Linen.** - Bed sheets and other linen used for the patients shall be changed daily.
- (7) Fire Fighting.** - Fire fighting system/equipments shall be installed as per government guidelines or fire NOC shall be obtained from competent authority, whichever applicable.
- (8) Quality Assurance.** - The names of the doctors working in the hospital and the facilities made available in the hospital shall be written and exhibited in the hospital. The Hospital shall strive to maintain quality in each of its services to be provided to the patients
- (9) Security.** - Due protective measures shall be undertaken by the Hospital to ensure safety of the patients, visitors, staff and their properties and to prevent child lifting etc.
- (10) Hospital accessories.** - Sufficient number of wheel chairs, trolleys, stretchers etc. shall be made available in the hospital.
- (11) Generator.** - A generator shall be provided to maintain essential services during power failure.
- (12) Labour Room.** - If the Hospital is maintaining a labour room and is conducting deliveries it shall have the following norms, namely:-
 - (a) Building.** - There shall be a room for preparation of the patient for delivery, giving enema etc., with sufficient water supply. The Labour room shall not be less than 120 square feet well ventilated with sufficient light. Space for keeping the newborn baby and for its resuscitation is essential.
 - (b) Staff.** - Delivery shall be conducted preferably by a qualified RMP. Otherwise Qualified Nurse, Auxiliary Nurse Midwife may do the same. Untrained persons shall not be entrusted with the Job. Even if a Nurse / Auxiliary Nurse Midwife conduct the delivery, a RMP shall be on call for any emergency or newborn resuscitation. If the labour ward is in a maternity hospital and deliveries are taking place regularly, a duty RMP shall be available round the clock. It is desirable to have a Paediatrician on call.
 - (c) Equipment.** - The following equipments and hospital accessories shall be made available, namely:-
 - (i) Labour Table with lithotomic stand
 - (ii) Saline Stand
 - (iii) Oxygen Cylinder with Vent mask
 - (iv) P.V. Tray with equipment
 - (v) Dilation & Curettage (C & A) Set
 - (vi) Focus Lamp
 - (vii) Trolleys for instrument and to receive the baby
 - (viii) Vacuum extractor / Forceps delivery set
 - (ix) Sterile cord clamp
 - (x) Antiseptic lotions
 - (xi) Suction apparatus
 - (xii) Baby resuscitation set
 - (xiii) Baby Warmer (a light may also do)
 - (xiv) Baby mucus sucker (disposable)
 - (xv) Paediatric ambu bag

(xvi) Suturing tray for episiotomy and suturing.

And any other equipment prescribed by State Government time to time under this rules.

(d) Drugs. -

- Injection Methergin	- Inj.Magnesiumsulphate
- Injection Pitocin	- Absorbable suture material
- Injection Carboprost	- Inj.Diazepam
- I.V. Fluids 5% dextrose bottles.	- 2% Lignocane
- Dextrose Normal Saline	- Disposable Syringe
- Ringer lactate.	- Injection Vitamin K
- Tab.Misoprostol 200mcg	- Injection Eptoin

And any other drugs prescribed by State Government time to time under this rules.

(e) Records. -

- (i) Birth Register (Hospital shall also register the details of new born baby on Health and Family Welfare Department platform.)
- (ii) Birth intimation slip
- (iii) Case sheets and notes to be recorded
- (iv) Register for babies and mothers to prevent child changing.

(13) Operation Theatre. -

(a) Minor Operation Theatre. - Where septic cases and minor surgeries like abscess, Incision and Drainage (I&D) and other septic cases etc. are carried out.

- (i) Space. -** Sufficient space - not less than 100 square feet with adequate lighting and ventilation.
- (ii) Staff. -** All surgeries in minor operation theatre shall be carried out by qualified doctor RMP only. However dressings can be done by a Qualified Nurse or a Trained Nurse.

(iii) Equipments. - Operation table.

- Focus light
- Sterilizer
- Auto clave
- Bins
- Saline Stand
- Minor surgical equipments
- Regional Anaesthesia equipment
- Sterile gloves
- Sterile syringes
- Drugs as required
- Drugs for emergency tray
- Boyle's apparatus with Oxygen cylinder, Nitrous Oxide Cylinder
- Suction apparatus
- Baby resuscitation set

And any other equipment prescribed by State Government time to time under this rules.

- (iv) **Records.** - Records of all surgeries done in minor operation theatre shall be entered in a register.

(b) Major Operation Theatre. -

- (i) **Space.** - Shall have sufficient space with a minimum of 150 square feet is essential, well lit preferably air-conditioned. Other than the operating room, there shall be provision for patient waiting and a cot provided for post-operative recovery. Sufficient space shall be available for autoclave and sterilization and for scrubbing. Running water from the tap shall be available in the scrub room sufficient arrangements for fumigation of operation theatre. Swab for culture to be taken from operation theatre at least once a month.
- (ii) **Staff.** - A qualified nurse shall be the head of nursing staff in the Operation Theatre. Anaesthesia to be provided by a qualified Anaesthetist or by a doctor only who is trained in anaesthesia as per the RCH programme guideline of NHM. Surgeries shall be performed by qualified doctors only.

(iii) Equipments. -

- Operating table
- Focus Light preferably wall mounted
- Boyle's apparatus with sufficient cylinders
- Monitoring devices including
 - (a) Multipara monitors
 - (b) Pulse Oximeters
- Suction apparatus preferably two
- Sterilizer, Autoclave
- Surgical equipments for surgery
- Sterile bin
- Stretcher for shifting of patient
- Anaesthesia station/trolley.

And any other equipment prescribed by State Government time to time under this rules.

- (iv) **Records.** - Record of all surgeries performed shall be available in a register duly with name, age, gender, address of patient, Surgeon, Anaesthetist and Staff Nurse also to be entered. Biopsy reports also shall be entered.

(14) Intensive Care Unit. - An Intensive Care Unit may be maintained in all Nursing Homes / Hospital having more than hundred beds. The following norms are to be maintained, namely:-

- (a) **Space.** - A well ventilated preferably air conditioned room with sufficient lighting is essential. For up to four ICU beds, a minimum space of 240 square feet and proportionately higher if the number of ICU beds is more. Sufficient space for keeping ventilators and monitors to be available. Space for duty RMP and nurse shall also be available. There shall be provision for attendants outside the Intensive Care Unit.
- (b) **Staff.** - One doctor for every ten beds for day time. If there are more than ten beds, one additional doctor for every additional ten beds. Similar provision shall be made for night time.
- (c) **Nurse.** - One qualified nurse for up to three beds shall be available round the clock. For every additional three beds a qualified nurse shall be available.
- (d) **Equipments. -**
 - Intensive Care Unit hospital beds

- Saline Stands
- Ventilators
- Multipara Monitors
- Pulse Oximeters
- Defibrillator
- Suction apparatus
- Oxygen supply (either Cylinder or central supply)
- Intubation equipments
- Drugs
- Generator

And any other equipment prescribed by State Government time to time under this rules.

- (e) **Records.** - A record of in-patients in Intensive Care Unit shall be available either in a manual register or electronically as to their illness, treatment offered, specialists visited - Out come etc.,

(15) Medical Record Maintenance in a Hospital. - The following records shall be maintained, namely:-

- (i) Admission and Discharge Register.
- (ii) Case sheets
- (iii) Referrals
- (iv) Infectious and Communicable disease Register.
- (v) Immunisation particulars
- (vi) Family Welfare Services
- (vii) Medico Legal Records
- (viii) Maternal Death Record
- (ix) Infant Death record
- (x) 1 to 5 years Child Death records
- (xi) Birth and Death Register (with cause of death)
- (xii) Any other record as may be required by the Government under any other Act/rules-regulations of Government of India or Government of Gujarat.
- (xiii) All the records as mentioned above may be kept electronically and to be linked with the public health record keeping as determined by Govt. authorities from time to time.

V. Dental Clinic. –

- (1) **Building.** - The consulting room if it accommodates the Dental Chair also shall be having sufficient space not less than 100 square feet. The room shall be well ventilated and shall have sufficient lighting arrangements. Space for keeping the Sterilizer and Trays to be provided. Sufficient space for patient waiting to be provided outside the consulting room.
- (2) **Staff.** - Dental Surgery, Consultation and prescription shall be performed by a qualified Dental Surgeon only as per the Indian Dentist Act, 1948 (Central Act XVI of 1948). Injections and administration of anaesthesia shall be done by the dental surgeon himself. X-Ray shall be taken by a qualified Radiographer or by the Dentist.
- (3) **Equipments.** - (a) Dental Chair
 (b) Provision of water for surgery
 (c) Sterilizer
 (d) Bin for sterile cotton gauze etc.

- (e) Trays with instruments
- (f) Dental instruments
- (g) X-Ray (desirable)
- (h) Disposable (optional) / autoclaved syringes.

And any other equipment prescribed by State Government time to time under this rules.

(4) Records. - A separate record shall be maintained as specified in the rules

- VI. Dental Hospitals.** - Out-patient department. - The outpatient department of a dental hospital shall conform to the norms prescribed to a Dental Clinic. In addition, sufficient waiting room shall be provided to the patients. Wards, Operation Theatre and other aspects shall be as per the norms prescribed to the nursing homes and hospitals.
- VII. Clinical Laboratories.** - Clinical Laboratories includes clinical laboratories, pathological laboratories, radiological centres, genetic laboratories etc.

(1) Building – Sufficient space for sample collection, Processing, Report preparation etc. should be available. There shall be sufficient space for Microscopy and for Biochemical tests. The room shall be well ventilated with sufficient light. Space for keeping a hospital bed for the use of patient shall be available. If x-ray is also functioning, norms as for an X ray centre shall be followed. The laboratories shall ensure adequate space in relation to the following:-

- (a) Patient's reception
- (b) Sample collection
- (c) Isolation for Bio hazardous materials
- (d) Radioisotope related work as per the regulatory agency Atomic Energy Regulatory Board (AERB) requirement.
- (e) Lavatory for the patients use at least one shall be available with sufficient water

The Laboratories shall preferably follow standards prescribed by the National Accreditation Board for Testing and Calibration of Laboratories for the personnel qualification etc., quality assurance in Lab Service, Internal Quality and External Quality should be ensured.

(2) Staff. – The laboratory work shall be supervised and approved by a qualified person specified in Annexure-9

(3) Equipments. -

- (a) Microscopes
- (b) Calorimeter
- (c) Centrifuge
- (d) Test Tubes
- (e) Slides
- (f) Reagent as needed
- (g) Semi Auto Analyzer or Auto Analyzer
- (h) Cell Counter
- (i) Hemoglobin meter
- (j) Counting Chambers etc.
- (k) Refrigerator
- (l) Hot Air oven
- (m) Physical Balance
- (n) Micro Pipettes fixed and variable volume
- (o) Bio safety cabinet

(P) Laminar air flow cabinet -Optional.

And any other equipment prescribed by State Government time to time under this rules.

(4) Records. - A separate record shall be maintained as specified in the rules

The following minimum Records to be maintained: -

- (a) Daily Results Register
- (b) Internal Quality Control Register
- (c) Sample Collection Register
- (d) Participation in External Quality Assessment Schemes/ Programmes.

VIII. X-Ray (Radiograph) and Imaging Centres. - This Centre shall include all centres of Imaging Sciences namely, Ultra Sonogram Scan Centres, Computed Tomography (C.T.) Scan Centres, Magnetic resonance imaging (MRI) Scan Centres, X-Rays (Radiograph) as well as and Treadmill Echocardiography etc.

1. Buildings. - Sufficient space as the equipment in use demands. Sufficient space shall be provided for patient waiting and resuscitation of the patient in case of any anaphylaxis occurring, during contrast injection or after a treadmill test patient feels like resting. X ray and imaging centres shall fulfil the "Atomic Energy Regulatory Board" (AERB) norms.

2. Staff. - All tests shall be carried out by qualified technical persons only as follows:-

X-Ray	Radiographer with Clinical Research Associate (CRA) Qualification or Diploma in Medical Radiology Imaging Technology or BSC in imaging Technology Or Degree or Diploma Course approved by AERB or Certificate/Diploma/Degree course as approved by State Government/University recognised by UGC.
Ultra Sonogram	by a qualified Doctor or by a Radiologist or Concerned Specialist as per the provisions of the Pre-Conception And Pre-Natal Diagnostic Techniques (Prohibition of Gender Selection) Act, 1994
Electro Cardiogram (ECG)	by an Electro Cardiogram (ECG) Technician trained in Electro Cardiogram (ECG)
Electroencephalography (EEG)	Electroencephalography (EEG) Technician trained in Electroencephalography (EEG)
Computed Tomography (CT) scan	By a Radiographer/ X-ray technician and report by a Radiologist or by the concerned specialist.
Treadmill	Concerned Technician. A doctor shall be present during the Test.
Echo Cardiograph	by a Qualified Doctor preferably a Cardiologist or by a Qualified Doctor (Post Graduate in field of Radiology, Medicine, Pediatric, Anesthesia, Emergency, Critical care, Clinical Cardiology with adequate experience preferably a Cardiologist (Super Specialist in field of Cardiology)
Contrast Studies	Radiologist or by the Concerned Specialist
Magnetic resonance imaging (MRI)	Radiologist or by the Concerned Specialist

Scan. – MRI/CT scan/PET scan/USG scan Ultra sonography scan reporting shall be performed by a Radiologist or by the Concerned Specialist.

2. Equipments. - Equipments according to the concerned speciality tests.

3. Records. - A separate record shall be maintained as specified in the rules.

IX. Laboratories:

S. No.	Type of Laboratory	Basic Composite	Medium	Advanced
(1)	(2)	(3)	(4)	(5)
I	Scope of Services	These tests (as mentioned below) can be performed in mobile laboratory at field locations also.	In addition to the tests performed in basic Composite laboratory, including tests mentioned as under.	In addition to tests performed in medium laboratory, additional tests mentioned as under.
	(a) Biochemistry	Routine Biochemistry tests like Blood Sugar, Renal Function Tests, Liver Function Tests, Amylase, Lipase, Lipid profile, Cerebro -Spinal Fluid (CSF) and other biological fluids (glucose and protein), Oral Glucose Tolerance Test, Electrolytes, Calcium or Phosphate, HbA1c, any bio chemistry based rapid test.	Hormone Bioassay, Tumor markers, plasma protein electrophoresis	(a) coagulation profile, Drug monitoring and toxicology assay, (b) Molecular genetics, tests for detection of inborn errors of metabolism
	(b) Haematology	Haemogram, Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching.	Coagulation Assay	All other Haematology tests also.
	(c) Histopathology	Nil	May do, subject to availability of equipment and specialist	Histopathology Examination
	(d) Molecular Genetics	Nil	May do, subject to availability of equipment and specialist	Molecular genetics
	(e) Cytopathology	Nil	PAP smear, Fine Needle Aspiration Cytology (FNAC), sputum and CSF cytology	Immuno Cytochemistry. Other biological fluid cytology; Ultrasound or CT guided FNAC.
	(f) Immunohistopathology	Nil	Nil	Immunohisto-chemistry:
	(g) Medical Microbiology & Immunology	Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova/ cyst. All HIV positive rapid Assays need to be confirmed from the next level diagnostic laboratory.	(a) Serological tests for viruses, bacteria, fungi, parasites (b) Cultural Sensitivity tests: Bacterial or fungal (c) Other special stains besides Gram's stain.	(a) Culture sensitivity tests for Bacteria. Real Time Polymerase Chain Reaction (RT-PCR) tests. (c) Tissue diagnosis test for infectious diseases.
II	INFRASTRUCTURE			
		Basic Composite	Medium	Advanced
	1. Signage			
	(a) Basic signage- A signage within or outside the facility should be made available containing	Essential	Essential	Essential

S. No.	Type of Laboratory	Basic Composite	Medium	Advanced
(1)	(2)	(3)	(4)	(5)
	the following information.			
	(b) Name of the person-in-charge with Qualification and registration number	Essential	Essential	Essential
	(c) Broad services Provided i.e. Haematology, Biochemistry Clinical Pathology, Histology, Cytology, Molecular Genetics- whichever is applicable	Essential	Essential	Essential
	(d) Timings of the different consultants	Desirable	Essential	Essential
	(e) Internet facility or Telephone and mobile number for appointment	Desirable	Desirable	Desirable
	(f) Fee structure: To be displayed separately including type of investigation and charges i.e. Special and routine tests	Essential	Essential	Essential
2.Safety Signage (Wherever applicable)				
	(a) Safety hazard and caution signs- Biomedical waste segregated in coloured bins and bags as per Biomedical Waste Management Rules, 2016 including radioactive materials, toxic chemicals, microbial agents, infected biological material.	Essential	Essential	Essential
	(b) Appropriate Fire exit signages - Minimum one fire extinguisher	Desirable	Desirable	Essential
3.Space requirement				
	(a) Registration and waiting room, public utilities, safe drinking water etc.	Desirable	Essential	Essential
	(b) Sample collection area	Essential	Essential	Essential
	(c) Laboratory with adequate diffuse and spot lighting	Essential	Essential	Essential
	(d) Toilet	Essential	Essential	Essential

S. No.	Type of Laboratory	Basic Composite	Medium	Advanced
(1)	(2)	(3)	(4)	(5)
	(e) Reporting and billing area	Essential	Essential	Essential
	(f) Staff room and doctor's duty room - Male and female different where 24 hours services available	Desirable	Desirable	Essential
	(g) Washing room	Essential	Essential	Essential
	(h) Preservation of the specimens and slides	Essential	Essential	Essential
	(i) Electrical facilities	Essential	Essential	Essential
	(j) Temperature control for specialized equipment like flow cytometry and chemiluminescence equipment, ELISA test equipment etc.	Essential	Essential	Essential
	(k) Counselling room for HIV	Essential, if HIV test is done	Essential, if HIV test is done	Essential, if HIV test is done
	(l) FNAC room for all patients for sample collection	Desirable	Desirable	Desirable
	(m) Darkroom for Immunofluorescence	Not required	Not required	Essential
	(n) Frozen Section facilities	Not applicable	Essential	Essential
	4. Furniture and fixtures	Essential	Essential as per scope of services	Essential as per scope of services
	5. Communication system - Telephone and mobile number for appointment	Desirable	Desirable	Desirable
	6. Wash Basins	Essential	Essential	Essential
	III. HUMAN RESOURCE			
	a) Minimum Qualification of Technical Head of Laboratory or Specialist *Authorised Signatories.	<p>Essential –</p> <p>1. MBBS registered with MCI or State Medical Council with at least one year training or work experience in a Medical Diagnostic Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation.</p> <p>NOTE:</p> <p>1. *The authorised signatory will be liable for authenticity of the laboratory report only.</p> <p>2. Medical tests should normally be undertaken on the advice of a registered medical practitioner.</p>	<p>Essential –</p> <p>1. Doctor of Medicine (MD) or Diplomate of National Board (DNB) in Pathology or Biochemistry or Medical Microbiology or Laboratory Medicine or Diploma in Clinical Pathology (DCP), registered with MCI or State Medical Council.</p> <p>Or</p> <p>2. MBBS with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having</p>	<p>Essential –</p> <p>1. Doctor of Medicine (MD) or Diplomate of National Board (DNB) in Pathology or Biochemistry or Medical Microbiology or Laboratory Medicine or Diploma in Clinical Pathology (DCP), registered with MCI or State Medical Council.</p> <p>Or</p> <p>2. MBBS with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology</p>

S. No.	Type of Laboratory	Basic Composite	Medium	Advanced
(1)	(2)	(3)	(4)	(5)
		<p>institution with at least three years training or work experience in a Medical Diagnostic Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of laboratory results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p>Note: <i>Laboratory technician with qualification as mentioned in Part III (b) of this table working in a Medical Diagnostic Laboratory registered under a Central or State Clinical Establishments Registration Act, as applicable, and a Health care worker in a Government National Health program trained for conducting identified specific tests, may conduct the tests and generate test results which shall be submitted to the signatory authority at Sl. Nos. 1 or 2 as applicable</i></p>	<p>experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate, sign and issue test reports in respect of tests of their respective specialty.</p> <p>Or M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p>Note: Interpretation of lab results or opinion there on, wherever required by the signatory authority at Sl. No.3, such test reports may be co-signed by the signatory authority at Sl. Nos. 1 or 2, after recording opinion or interpretation. Co-signee medical doctor shall be responsible only for the opinion or interpretation given.</p>	<p>of tests of their respective specialty.</p> <p>Or M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p>Note: Interpretation of lab results or opinion there on, wherever required by the signatory authority at Sl. No.3, such test reports may be co-signed by the signatory authority at Sl. Nos.1 or 2, after recording opinion or interpretation. Co-signee medical doctor shall be responsible only for the opinion or interpretation given.</p> <p>Desirable: If any special test* of other speciality is done, it</p>

S. No.	Type of Laboratory	Basic Composite	Medium	Advanced
(1)	(2)	(3)	(4)	(5)
		<p>Desirable: If any special test of other speciality is done, it is desirable that specialist of that subject needs be there on full time or part time or outsourced basis.</p> <p>*Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory.</p> <p>Illustration: (i) Special Tests pertaining to Bio-Chemistry and Micro-biology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively.</p> <p>(ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Pathology.</p>	is desirable that specialist of that subject needs be there on full time or part time or outsourced basis. *Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory. Illustration: Special Tests pertaining to Bio-Chemistry and Micro-biology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively. (ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Pathology.	
	(b) Number of laboratory technicians with Diploma in Medical Laboratory Technology (DMLT) or Bachelor of Science (B.Sc.) Medical Laboratory Technology (MLT) or Master of Science (M.Sc) Bio-chemistry or Micro biology qualification from a recognised university or institution.	Essential: 1	Essential: 2	Essential: 4
	(c) Support staff (Laboratory Assistant or Laboratory Attendant) Roster of salary of staff. Periodic health check-ups and vaccination of staff.	Essential: 1	Essential: 1	Essential: 2”.

B. AYUSH

I. CONSULTING ROOM / CLINIC / POLYCLINICS

1. ***Building.***- The Consulting room shall be spacious, well ventilated and having sufficient light. The space shall be not less than 100 square feet. There shall be sufficient space for waiting of the patients etc., If it is a polyclinic, different cubicles shall be available for each doctor. The names of visiting doctors and their system of medicine shall be exhibited in front of the clinic.
2. ***Staff.***- The clinics namely, Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy Clinics shall be manned by the registered Medical practitioner . If the pharmacy attached with the clinic, dispensing of medicines shall be done by a Pharmacist qualified under the respective system or by the doctor himself.
3. ***Equipment.*** - Diagnostic equipments ordinarily needed for all AYUSH, Indian System of Medicine and Homeopathy and Yoga and Naturopathy Clinics:
 - (i) Thermometer
 - (ii) Sphygmomanometer
 - (iii) Stethoscope
 - (iv) Knee hammer
 - (v) Tongue Depressor
 - (vi) Torch
 - (vii) Weighing machine
4. ***Drugs.***-The drugs dispensed to the patients shall contain a label indicating the name of medicine and the name of patient to whom it is given and quantity to be given etc., the date of expiry shall be specified in the label, if the drug has an expiry date. The drug to be given internally and the drug to be used externally shall be indicated and white and red labels to be provided respectively with clear writing as “For Internal use” or “ For External Use” in vernacular.,
5. ***Records.*** - A record of all patients seen as to their name, age, sex, diagnosis and treatment shall be available. The patient shall be provided with a slip with name, age, sex, diagnosis of treatment given.

II. NURSING HOMES AND HOSPITALS.-

1. ***Building.*** - The norms prescribed for consulting room or outpatient in the Allopathy system of medicine shall be fulfilled. It shall also have sufficient space for patient waiting separate cubicles for each doctors to work. The names of the doctors and then Specialists and different facilities available in the hospital shall be put up in a board.
2. ***Wards or inpatient rooms.*** - Inpatient wards shall be spacious with ventilation and lighting. Electric fan shall be provided to each room and in common rooms one fan for at least four beds shall be provided. Toilets be common or separate but shall be clean and provided with water from tap. Cleaning arrangements shall be made to swab daily the wards with antiseptic lotion.
3. ***Staff. - (a) Doctors.*** - The hospital shall employ only registered medical practitioner to treat the patients. The doctor shall also be registered in the Council under his respective system of medicine or in the Council/Board for Indian System of Medicine.
 - (b) ***Nurse.*** - A qualified nurse shall be available at the ratio of one nurse and two trained nurses for up to thirty beds.
 - (c) ***Pharmacist/Therapist.*** - Pharmacist/Therapist qualified or trained in the respective system of medicine shall be employed for dispensing of medicines. If the hospital has more than thirty beds, for less than thirty beds the doctor himself can dispense the medicines or employ a qualified or trained pharmacist/Therapist.

(d) ***Other Staff.*** - Other staff shall be employed as per need. Sufficient number of cleaning staff shall be available at least one for every thirty beds.

4. *Equipment.-*

(a) The following Exercise Therapy equipments shall ordinarily needed for all Siddha Hospitals, namely:-

- (i) Traction Kit
- (ii) Walker
- (iii) IR light
- (iv) TFT and Ultrasound Therapy Instrument
- (v) Vibrator (Manual and Electronic)

(b) The following equipments ordinarily required for all Siddha Hospitals, namely:-

- (i) Thokkanam table
- (ii) Vedhu Chamber
- (iii) Wax bath machine
- (iv) Karanool
- (v) Kazhichal endhiram
- (vi) Vaanathi maruthuvam Chair
- (vii) Nasiyam Chair
- (viii) Peetchuendiram-Disposal Packs
- (ix) Kidney Tray
- (x) Motion tray
- (xi) Nebuliser Set
- (xii) Moving Stretcher
- (xiii) Disposable Syringes
- (xiv) Surgical instruments for common procedures, First Aid
- (xv) Parenteral drugs and infusion related equipments
- (xvi) Equipments needed for specific Aga maruthuvam, puramaruthuvam procedures.

(c) *Equipments for Yoga and Naturopathy.-*

Yoga Therapy.-

- (i) Carpets /coir mats
- (ii) Jala neti pot
- (iii) Eye wash cup
- (iv) Yoga charts
- (v) Sutra neti rubber catheter

Hydrotherapy.-

- (i) Enema can
- (ii) Steam bath cabin with Automatic steam generator
- (iii) Facial sauna
- (iv) Fomentation bag

- (v) Ice bag
- (vi) Packs – Chest, Leg, Arm, Knee, Abdomen, GH Pack, Renal, Full wet sheet pack
- (vii) Linen cloth for compress
- (viii) Epsom salt-packets
- (ix) Hip bath tub
- (x) Spinal bath tub
- (xi) Spinal Spray
- (xii) Foot and arm bath tub
- (xiii) Small and Big towels

Mud Therapy.-

- (i) Mud storers-100 lts barrel-2
- (ii) Linen cloth- for preparing mudpacks
- (iii) Mud trays
- (iv) Bucket and mug-2

Magneto Therapy.-

- (i) High, Medium, Low power magnets with keepers
- (ii) Magnetic belt – Neck, Abdomen, Knee, Wrist

Massage Therapy.-

- (i) Massage table-cushioned and covered with rexin
- (ii) Foot stepper
- (iii) Vibratory massager
- (iv) Roller massager

Chromotherapy.-

- (i) Colour lamps
- (ii) Colour glass bottles
- (iii) Color Thermoleum

Electrotherapy.-

Infra-red lamp (IRR) Acupuncture/Acupressure.-

- (i) Moxa stick
- (ii) Electronic Acu – stimulator
- (iii) Reflexology chart
- (iv) Acu-Roller-Spinal, Spinal, Palm, Soles, Legs, Fingers
- (v) Acupuncture needles- copper-(0.25x25)

5. *Physical fitness*

- (i) Static cycle
- (ii) Manual Treadmill
- (iii) Rowing machine
- (iv) Overhead pulleys

6. **Infrastructure.** - Clinic shall have the consultation items and minimum equipments to give out patient treatments. Hospital shall have all the equipments along with diet centre to prepare bland diet, natural diet, herbal juice and other special diet therapy for various diseases. In addition to above, first aid and emergency management need to be provided. Sufficient number of Wheel Chairs, Stretchers shall be available at least one per every thirty beds.
7. **Records.** - (1) A record of all patients admitted / treated shall be available along with the investigations diagnosis and treatment. The patient shall be provided with a discharge slip containing the details of investigation, diagnosis, treatment and follow up etc.,
 (2) The following register shall be maintained. It is the duty of the clinical establishment to give all the relevant particulars to the patients on demands.
 - (i) Admission and Discharge Register
 - (ii) Contagious and infectious disease register.
 - (iii) Medico legal cases register (in case medico legal cases are brought there for treatment at any stage), if applicable
 - (iv) Birth and Death Register, if applicable

Records with full address shall be kept ready for verification by the District Authority/State Council/Health and Family Welfare Department.

C. GENERAL CONDITIONS TO BE FULFILLED BY THE HOSPITALS UNDER AYUSH.

- 1. Security.** - Sufficient security shall be provided for the safety of inmates and to prevent theft.
- 2. Fire Fighting:** - Fire fighting equipment with I.S.I. mark shall be provided as per rules in the hospital.
- 3. Kitchen.** - If food is provided to inmates, the kitchen shall be clean and the cook(s) shall be periodically, medically examined for any infection or contagious diseases.
- 4. Clothing and Linen.** - It shall be clean and changed daily.
- 5. Water Supply.** - The potable water shall be provided to the patient.
- 7. Waste Disposal.** - It shall be as per the Government of India norms and shall follow the guidelines of Gujarat Pollution Control Board.

Annexure-10

(see rule 15)

Part A.

Register of Laboratory Test Conducted

System of Medicine:

Clinical Laboratory:

Gujarat Clinical Establishment

(Registration and Regulation) Act

Registration no. :

Date:

Sr.No	Name of the Patient and address	Mobile No.	Age	Gender	ID No.	Referring Doctor
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.						
2.						
3.						

Provisional Diagnosis	Investigations Specimen	Investigation performed	Method of Investigation and Equipment	Result	Additional information if any	Initial of the Medical Officer
(8)	(9)	(10)	(11)	(12)	(13)	(14)

Note: If electronic records are maintained and / or existing registers capture this information, a monthly print outs / copy shall be taken and signed by the authorities concerned.

Part B

Indoor Patients Register

System of Medicine _____ Hospital / Nursing Home

Gujarat Clinical Establishments Regulation Act Registration no. :

S. No.	Name of the Patient and address	Mobile No.	Age	Gender	Hospital IP No.	Date and Time of Admission	Provisional Diagnosis
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.							
2.							
3.							
4.							

Investigations if any	Final diagnosis	Treatment	Date of Discharge	Result Cured / Same condition / Referred / Expired	Additional information if any	Initial of the medical officer
(9)	(10)	(11)	(12)	(13)	(14)	(15)

Note: If electronic records are maintained and / or existing registers capture this information, a monthly print outs / copy shall be taken and signed by the Hospital authorities.

- The hospital shall maintain individual case sheets for the patients.

Part C

Register of Out door Patients

System of Medicine

Clinic / Consulting Room

**Gujarat Clinical Establishment Regulation Act
Registration no.:**

Name of the Doctor:

Date:

Serial No	Name of the Patient and address	Mobile No./ Contact No. if available	Age	Gender	Provisional Diagnosis
(1)	(2)	(3)	(4)	(5)	(6)
1.					
2.					
3.					
4.					

Investigations if any	Final diagnosis	Treatment	Result Cured / Same condition / Referred / Expired	Additional information if any	Initial of the Medical officer
(7)	(8)	(9)	(10)	(11)	(12)

Note: If electronic records are maintained and / or existing registers capture this information, a monthly print outs / copy shall be taken authenticated by the Hospital authorities

Part-D

Operation Register

System of Medicine:

Hospital / Nursing

Gujarat Clinical Establishment Regulation Act

Registration no.:

Operation Theatre (Please specify the OT either Maternity / General/ Ortho etc., as the case may be)

Operation/Procedure performed (10)	Name of Operating Surgeon and Assistant (11)	Name of Anaesthetist (12)	Name of Staff Nurse Assisted (13)	Operation-Time (From to) (14)	Opration Notes (15)	Transferred to which ward (16)	Additional information if any (17)	Initial of the Medical officer (18)

Note: If electronic records are maintained, and / or existing registers capture this information, a monthly print outs / copy shall be taken and it shall be authenticated by the Hospital authorities.

Annexure-11

(See rule 16)

Form-A

List of Clinical Establishments

Period – 1st January, to 31st December,

Serial No.	Name and Address of Clinical Establishment (2)	GCERA No. and Date (3)	District (4)	Type of Establishment (5)	Validity Period (6)	
					From	To
(1)	(2)	(3)	(4)	(5)		
1.						
2.						
3.						
4.						
5.						
6.						
7.						

Form-B

List of Clinical Establishments with Expiry of Registration

Serial No.	Name and Address of Clinical Establishment (2)	GCERA No. and Date (3)	District (4)	Type of Establishment (5)	Type of Registration (6)	Registration Expired on (7)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.						
2.						
3.						
4.						
5.						
6.						
7.						

Annexure-12**(Check list for inspection)***(See rule 17)***A. Allopathy System****I. Consulting Room. -****(1) Infrastructure –**

Adequate space	Yes/No
Adequate light	Yes/No
Adequate ventilation	Yes/No
Patients waiting area facility	Yes/No

(2) Staff. - registered medical practitioner available. Yes/Noregistered qualified nurse available. **Yes/No****(3) Equipment. - The following equipment and hospital accessories shall be available in the consulting room, namely: -**

(a) Examination couch/ table	Yes/No
(b) Blood Pressure Apparatus	Yes/No
(c) Stethoscope	Yes/No
(d) Torch light	Yes/No
(e) Thermometer	Yes/No
(f) Weighing Machine	Yes/No
(g) Knee hammer	Yes/No
(h) Measuring tape	Yes/No
(i) Special examination trays for specialist like proctoscopy, Pelvic Exam Tray(P.V. Tray), Eye testing screen and Ear-Nose Throat examination trays as the case may be available.	Yes/No
(j) Curtain/screen for sufficient privacy of the patient	Yes/No;

(4) Records. –Patients' Register with details as per Annexure 10(preferably electronically) **Yes/No****(5) Prescription slip. – date, name of patient, legible recommendation of drug/drugs with dose and duration, stamp/seal of RMP. **Yes/No******II. Clinic. - In addition to consulting room, the following checklist are require to be fulfilled****(1) Infrastructure -**Sufficient space for two hospital beds for managing emergency/ primary treatment of patient **Yes/No****(2) Staff. –**

1	Registered Medical Practitioner (RMP)	Yes/No
2	Qualified nurse	Yes/No
3	Cleaning personnel	Yes/No

(3) **Equipments.** –

(a) Sterilizer or autoclave;	Yes/No
(b) Arrangement for getting autoclaved or sterilized syringes / instruments or shall use only disposable syringes;	Yes/No
(c) Sterile Gloves;	Yes/No
(d) Cheatle Forceps;	Yes/No
(e) Scissors surgical;	Yes/No
(f) Adhesive plaster;	Yes/No
(g) Suturing trays with equipment;	Yes/No
(h) Kidney trays;	Yes/No
(i) Surgical equipments for abscess Incision and Drainage etc.	Yes/No
(j) Drugs as applicable	Yes/No

(4) **Waste Disposal.** – Facilities as per the Government of India and Gujarat Pollution Control Board norms.
Yes/No

(5) **Dispensation of Medicine.** – done by

1	Registered Medical Practitioner (RMP)	Yes/No
2	Qualified pharmacist	Yes/No

- (6) **Laboratory in a Clinic.** - supervise by qualified person as preferably Post graduate doctor in discipline of pathology, microbiology and Biochemistry. **Yes/No**
- (7) **X-ray Unit.** - Qualified technical person recognized by the Government. **Yes/No**
- (8) **Minor Surgeries.** –(refer to minor Operation Theater)In case of minor surgeries like cyst excision, Medical Termination of Pregnancy (MTP), Dilatation and Curettage (D&C) are undertaken it is advisable to have a sterile room for the purpose and facilities available as given for minor Operation Theatre.

III. Polyclinic. –

- (1) **Infrastructure** - (1) In addition to the norms prescribed for clinic and consulting room, separate cubicles/rooms/spaces available **Yes/No**
 (2) Reasonable space for waiting room **Yes/No**
 (3) Safe drinking water. **Yes/No**
 (4) Names of different Registered Medical Practitioner (RMP) attending shall be exhibited in the waiting room. **Yes/No**

IV. Hospital. –

- (1) a. **Infrastructure.** - In addition to the norms prescribed for Clinic, Consulting room and Polyclinic, the waiting room shall be made available for the patients/those accompanying them, which shall have sufficient space. **Yes/No**

b. **Wards or in-patient room clusters.** –

1	Adequate space	Yes/No
2	Adequate light	Yes/No
3	Adequate ventilation	Yes/No
4	Electric fan/Air cooler/Air conditioner in each room	Yes/No
5	One electric fan per two bed in common room/Air cooler/Air conditioner	Yes/No
6	Toilets common/separate provided with adequate water supply	Yes/No
7	Cleaning of Toilets daily with antiseptic liquid.	Yes/No
8	Cleaning of the wards daily with antiseptic liquid.	Yes/No
9	A duty room per twenty rooms with necessary Equipment like Oxygen, Saline Stand etc.	Yes/No

(2) **Staff.** – Specialist doctors for each specialist services provided in hospital. **Yes/No**

(i) **One RMP for every thirty beds physically available on duty**

During day **Yes/No**,

during night **Yes/No** and

- One RMP shall be on call duty up to thirty beds during night and off duty hours. **Yes/No**
- On duty RMP is available in the hospital physically for thirty beds and above in general side for all the 24 hours. **Yes/No**
- If the hospital is having a functional Intensive Care Unit then, one RMP is be available physically in ICU for 24/7 **Yes/No**

(ii) **Nurses.** – Three qualified nurse shall be available round the clock for up to thirty beds in a clinical establishment and then for each additional ten beds one qualified nurse shall be available. **Yes/No**

The aforesaid human resource is the minimum requirement irrespective of the fact the availability of any number of trained personnel working in the hospital.

(iii) **Cleaning Services.** –One sweeper/sanitary worker per thirty beds is available round the clock. **Yes/No**

(3) **Other Services. -**

(a) **Pharmacy.** - If a pharmacy is maintained in the hospital for dispensing medicines to the patients, Does the pharmacy unit follow the rules and guidelines of government? **Yes/No**.

(b) **Laboratory.** - If a Laboratory is maintained by the hospital, other than urine albumin, sugar, blood hemoglobin, all other Laboratory Tests shall be performed by a qualified Laboratory Technician. **Yes/No**

(c) **X-Ray (Radiograph).** - X-Rays taken by a qualified Technician. **Yes/No**

(d) **Scan.** – MRI/CT scan/PET scan/Doppler/ Ultra sonography scanning shall be performed by a Doctor only. **Yes/No**

(e) **Blood Bank** - If a blood bank is maintained by a hospital, it shall confirm to the standards/requirements as issued by the Government of India from time to time. **Yes/No**

(f) **Ambulance.** – (Hospital having fifty or more beds)

Own ambulance with qualified driver is available. **Yes/No**

Or

tie up (MoU) arrangement with another Hospital having Ambulance or some Ambulance service unit. **Yes/No**

(g) **Catering and Canteen.** - If available,

(1) Cleaning of the Kitchen daily **Yes/No**

(2) The cooks periodically medically examined **Yes/No**.

(3) FSSAI standards followed as issued by government time to time. **Yes/No**

(h) **General facilities.**

(i) **Waste disposal.** –(Government of India norms and Guidelines issued by Pollution Control Board).

Proper segregation of the waste at the point **Yes/No**.

(ii) **Record Keeping.** –as prescribe in the form of A,B,C,D in Annexure-10 and as per guidelines of state and central government time to time. **Yes/No**

(b) A medical case record shall be maintained for in the form of a register or electronically in the clinical establishment in respect of each patient, which shall include the following particulars, namely: -

(i) A detailed daily statement of the patient's health and condition.

- (ii) Details of any investigations made, surgical operations carried out and treatment given and
- (iii) Records of all medical prescriptions, Copy of detail reporting of any scan X-Ray reports, laboratory reports or any other report with full name, qualifications of the doctor.
- (iv) In the case of a maternity home or a maternity case, the said person shall keep a case record of each child born to a patient. Full and detail record of pregnancy must be maintained for at least a period of ten years.

In non MLC case if patient or his or her relative demand scan (USG/CT/MRI) you can give it in writing form in case paper but same time clinical establishment have to keep reporting of same scan in case paper

(iii) Medico Legal Cases. –record keeping of medico legal case as per government guidelines **Yes/No**,

- (4) Mortuary room.** – (A hospital having more than fifty beds)
a mortuary room. **Yes/No**,

or

room with freezer box facilities for the dead bodies. **Yes/No**

- (5) Water Supply.** –

- (1) Potable water supply is available. **Yes/No**.
- (2) Hot water supply is available. **Yes/No**

- (6) Clothing and Linen.** - Bed sheets and other linen used for the patients changed daily **Yes/No**.

- (7) Fire Fighting.** - Firefighting equipments/system shall be installed as per The Gujarat Fire Prevention and Life safety Measures Act, 2013 in force. **Yes/No**

- (8) Quality Assurance.** - The names of the RMPs working in the hospital and the facilities made available in the hospital shall be written and exhibited in the hospital. **Yes/No**

- (9) Security.** –Security measure for safety of patients and their properties and to prevent child lifting etc. **Yes/No**

- (10) Hospital accessories.** - Sufficient number of wheel chairs, trolleys, and stretchers shall be made available in the hospital. **Yes/No**

- (11) Generator.** - A generator in working condition as per requirement of hospital to maintain essential services during power failure. **Yes/No**

- (12) Labour Room.** - If the Hospital is maintaining a labour room and is conducting deliveries it shall have the following norms, namely:-

(a) Infrastructure –

- (1) There shall be a room for preparation of the patient for delivery, giving enema etc., with sufficient water supply. **Yes/No**
- (2) The area of Labour room is equal or more than 120 square feet. **Yes/No**
- (3) With well-ventilated and sufficient light. **Yes/No**.
- (4) Space for keeping the newborn baby with resuscitation. **Yes/No**

(b) Staff. – Delivery conducted by (tick right in available)

1	A qualified RMP	
2	Staff Nurse	
3	Auxiliary Nurse Midwife	

- (1) RMP available on call for any emergency or newborn resuscitation. **Yes/No**

- (2) If the labour ward is in a maternity hospital and deliveries are taking place regularly, a duty RMP shall be available round the clock. **Yes/No**.

- (3) Paediatrician on call available. **Yes/No**

(c) Equipment. - The following equipments and hospital accessories shall be made available, namely :-(tick right in available)

(i) Labour Table with lithotomic stand	
(ii) Saline Stand	
(iii) Oxygen Cylinder with Vent mask	
(iv) P.V. Tray with equipment	
(v) Dilation & Curettage (C & A) Set	
(vi) Focus Lamp	
(vii) Trolleys for instrument and to receive the baby	
(viii) Vacuum extractor / Forceps delivery set	
(ix) Sterile cord clamp	
(x) Antiseptic lotions	
(xi) Suction apparatus	
(xii) Baby resuscitation set	
(xiii) Baby Warmer (a light may also do)	
(xiv) Baby mucus sucker (disposable)	
(xv) Paediatric ambu bag	
(xvi) Suturing tray for episiotomy and suturing.	

(d) Drugs. -(tick right in available)

- Injection Methergin
- Injection Pitocin
- Injection Carboprost
- I.V. Fluids 5% dextrose
- Dextrose Normal Saline
- Ringer lactate.
Tab.Misoprostol 200mcg
Inj.Magnesium sulphate
Absorbable suture material
- Inj.Diazepam
- 2% Lignocaine
- Disposable Syringe
- Injection Vitamin K
- Injection Eptoin

(e) Records. -(tick right in available)

(i) Birth Register	
(ii) Birth intimation slip	
(iii) Case sheets and notes to be recorded	
(iv) Register for babies and mothers to prevent child changing.	

(13) Operation Theatre. -

(a) Minor Operation Theatre. - Where septic cases and minor surgeries like abscess, Incision and Drainage (I&D) and other septic cases etc., are carried out.

(i) Infrastructure-

- (1) Space - not less than 100 square feet. **Yes/No**
- (2) Adequate lighting. **Yes/No**
- (3) Adequate ventilation. **Yes/No**

(ii) Staff. -

- (1) Surgeries carried out by qualified RMP. **Yes/No**
- (2) Qualified Nurse allocated. **Yes/No**

(iii) Equipments. -

Operation table.	
Focus light	
Sterilizer	
Auto clave	
Bins	
Saline Stand	
Minor surgical equipments	
Regional Anaesthesia equipment	
Sterile gloves	
Sterile syringes	
Drugs as required	
Drugs for emergency tray	
Boyle's apparatus with Oxygen cylinder, Nitrous Oxide Cylinder	
Suction apparatus	
Baby resuscitation set	

(iv) Records. -

Register of Records of all surgeries done in minor OT available. **Yes/No**

(b) Main Operation Theatre. -**(i) Space. -**

- (1) Space with a minimum of 150 square feet. **Yes/No**
- (2) well air-conditioned available in main OT. **Yes/No**
- (3) Patient waiting area available. **Yes/No**
- (4) A cot(bed) provided for postoperative recovery. **Yes/No**
- (5) Sufficient space for autoclave and sterilization and for scrubbing. **Yes/No**
- (6) Running water from the tap in the scrub room. **Yes/No**
- (7) Sufficient arrangements for fumigation of operation theatre. **Yes/No**
- (8) Swab for culture to be taken from operation theatre at least once a month (register availbale). **Yes/No**

(ii) Staff. -

- (1) A qualified Anaesthetist or a doctor only who is trained in anaesthesia. **Yes/No**
- (2) Surgeries shall be performed by qualified doctors only. **Yes/No**
- (3) Head of nursing staff in the Operation Theatre. **Yes/No**

(iii) Equipments. –

Operating table	
Focus Light preferably wall mounted	
Boyle's apparatus with sufficient cylinders	
Monitoring devices including	
(a) Multipara monitors	
(b) Pulse Oximeters	
(c) Others	
Suction apparatus preferably two	
Sterilizer, Autoclave	
Surgical equipments for surgery	
Sterile bin	
Stretcher for shifting of patient	
Anaesthesia Kit.	
Defibrillator	

(iv) Records as per form part-D of Annexure-10 (operation register). **Yes/No**(1) Record of Biopsy reports (In cases whereas required) entered in register. **Yes/No**

(14) Intensive Care Unit. - An Intensive Care Unit may be maintained in all Nursing Homes / Hospital having more than hundred beds. The following norms are to be maintained, namely:-

(a) Space. –

- (1) For up to four hospital beds, a minimum space of 240 square feet and proportionately higher if the number of hospital beds is more. **Yes/No**
- (2) A well ventilated preferably air conditioned room. **Yes/No**
- (3) Sufficient lighting. **Yes/No**
- (4) Sufficient space for keeping ventilators and monitors available. **Yes/No**
- (5) Space for duty RMP available. **Yes/No**
- (6) Space for duty nurse/nurses available. **Yes/No**
- (7) Provision for attendants outside the Intensive Care Unit. **Yes/No**

(b) Staff. –

- (1) One doctor for every ten beds for day time physically available. **Yes/No**
- (2) If there are more than ten beds, one additional doctor for every additional ten beds physically available. **Yes/No**
- (3) Similar provision for night time physically available. **Yes/No**

(c) Nurse. –

- (1) One qualified nurse available for up to three beds for round the clock. **Yes/No**
- (2) An another qualified nurse available for every additional three beds. **Yes/No**
- (3) Similar arrangement available for night time. **Yes/No**

(d) Equipments. -

Intensive Care Unit hospital beds	
Saline Stands	
Ventilators	
Multipara Monitor	

Pulse Oximeter	
Defibrillator	
Suction apparatus	
Oxygen supply (either Cylinder or central supply)	
Intubation equipments	
Drugs	
Generator/Power backup	

- (e) **Records.** –Maintainence of record of in-patients in Intensive Care Unit as to their illness, treatment offered, specialists visited - Out come etc.available. **Yes/No**

(15) **Medical Record Maintenance in a Hospital.** - The following records shall be maintained, namely:-

Medical Record Maintenance in a Hospital	Electronically	Manually
(i) Admission and Discharge Register.		
(ii) Case sheets		
(iii) Referrals		
(iv) Infectious and Communicable disease Register.		
(v) Immunisation particulars		
(vi) Family Welfare Services		
(vii) Medico Legal Records		
(viii) Maternal Death Record		
(ix) Infant Death record		
(x) 1 to 5 years Child Death records		
(xi) Any other record as may be required by the Government, from time to time.		
Any other record as may be required by the Government under any other Act/rules-regulations of Government of India or Government of Gujarat.		

V. **Dental Clinic.** –

(1) **Infrastructure-**

- (1) Sufficient space of the consulting room not less than 100 square feet if it accommodates the Dental Chair. **Yes/No**
- (2) Well ventilated consulting room. **Yes/No**
- (3) Sufficient lighting arrangements. **Yes/No**
- (4) Space for keeping the Sterilizer and Tray. **Yes/No**
- (5) Sufficient space for patient waiting outside the consulting room. **Yes/No**

(2) **Staff. –**

- (1) Performance of Dental Surgery, Consultation and prescription by a qualified Dental Surgeon only as per the Indian Dentist Act, 1948 (Central Act XVI of 1948). _____ (Name of Doctor/Doctors and designation)
- (2) Injections and administration of anaesthesia shall be done by the dental surgeon. _____ (Name of Doctor/Doctors and designation)
- (3) X-Ray shall be taken by a qualified Radiographer or by the Dentist himself? _____ (Name of Doctor/Qualified Radiographer and designation)

(3) Equipments. -

(a) Dental Chair	
(b) Provision of water for surgery	
(c) Steriliser	
(d) Bin for sterile cotton gauze etc.	
(e) Trays with instruments	
(f) Dental instruments	
(g) X-Ray (desirable)	
(h) Disposable (optional) / autoclaved syringes.	

(4) Records. -

A record of the patients treated along with name, age, gender, disease and treatment given shall be available. A slip shall be given to the patient with all the above particulars. All the records as mentioned above may be kept electronically and to be linked with the public health record keeping as determined by Govt. authorities from time to time Available? **Yes/No**

VI. Dental Hospitals. - Out-patient department. - The outpatient department of a dental hospital shall confirm to the norms prescribed to a Dental Clinic. In addition, sufficient waiting room shall be provided to the patients. Wards, Operation Theatre and other aspects shall be as per the norms prescribed to the nursing homes and hospitals.

VII. Clinical Laboratories. - They shall include clinical laboratories, pathological laboratories, radiological centres, genetic laboratories etc.

- (1) Infrastructure- (1) Sufficient space for sample collection, Processing, Report preparation etc. **Yes/No**
- (2) Lavatories for the patients use with sufficient water. **Yes/No**
- (3) Sufficient space for Microscopy and for Biochemical tests. **Yes/No**
- (4) The room with well ventilated and sufficient light. **Yes/No**
- (5) Space for keeping a hospital bed for the use of patient available. **Yes/No**
- (6) If x ray is also functioning, norms as for an X ray centre shall be followed. **Yes/No**
- (7) The laboratories shall ensure adequate space in relation to the following:-
 - (a) Patient's reception area available. **Yes/No**
 - (b) Sample collection area available. **Yes/No**
 - (c) Area available for Isolation for Bio hazardous materials. **Yes/No**
 - (d) Radioisotope related work as per the regulatory agency Atomic Energy Regulatory Board (AERB) requirement.(if apply) **Yes/No**

The Laboratories shall preferably follow standards prescribed by the National Accreditation Board for Testing and Calibration of Laboratories for the personnel qualification etc., quality assurance in Lab Service, Internal Quality and External Quality should be ensured.

(2) Staff. -**(a) Examination/Reporting**

- (a) The Biopsy examination and reporting shall be done by a Pathologist or by a Trained Doctor.(If applicable) **Yes/No**
- (b) Culture and sensitivity tests carried out, a Microbiologist either Medical or non-Medical? (If applicable) **Yes/No**
- (c) Cytology reports given by a Pathologist only. **Yes/No**

(b) Qualification for technical staff. - The staff performing the technical tests shall have the

- (i) Diploma in laboratory technician; or
- (ii) Medical Laboratory Technician course; or
- (iii) Medical Technology; or
- (iv) Post graduate diploma in medical Laboratory Technology; or

- (v) One year medical laboratory technician training course; or
- (vi) Laboratory Technician Trainig course from any of Government recognised institution or University established or incorporated by or under the Central or State Act in India or any other educational institution recognised as such or declared to be deemed as a University under section 3 of the University Grant Commission Act,1956.
- (c) In a genetic laboratory, all tests shall be carried out and reporting done by a qualified Genetist or qualified doctor only. If amniocentesis is done as permitted by law it shall be done only in a Minor Operation Theatre and all facilities as needed for a Minor Operation Theatre shall be available and it shall be done by a qualified doctor under sterile conditions only.

(3) Equipments. -

(a) Microscopes	
(b) Calorimeter	
(c) Centrifuge	
(d) Test Tubes	
(e) Slides	
(f) Reagent as needed	
(g) Semi Auto Analyser or Auto Analyser	
(h) Cell Counter	
(i) Haemoglobin meter	
(j) Counting Chambers	
(k) Refrigerator	
(l) Hot Air oven	
(m) Physical Balance	
(n) Micro Puppets fixed and variable volume	
(o) Biosafety cabinet	
(P) Laminar air flow cabinet -Optional.	

- (4) Records. -** All tests carried out on the Laboratory shall be recorded in a Register along with name, age, gender, investigation done report, date, etc., All the records as mentioned above may be kept electronically and to be linked with the public health record keeping as determined by Govt. authorities from time to time.(As per prescribed in form part A of Annexure-10 Available? **Yes/No**

The following minimum Records to be maintained: -

- (a) Daily Results Register. **Yes/No**
- (b) Internal Quality Control Register. **Yes/No**
- (c) Sample Collection Register. **Yes/No**
- (d) Participation in External Quality Assessment Schemes Programmes. **Yes/No**

VIII. X-Ray (Radiograph) Centres. - This Centre shall include all centres of Imaging, Sciences namely, Ultra Sonogram Scan Centres, Computed Tomography (C.T.) Scan Centres, Magnetic resonance imaging (MRI) Scan Centres, X-Rays (Radiograph) as well as Electro Cardiogram (ECG), Electroencephalography (EEG) and Treadmill Echocardiography.

1. **Buildings. -** Sufficient space as the equipment in use demands. Sufficient space shall be provided for patient waiting and resuscitation of the patient in case of any anaphylaxis occurring, during contrast injection or after a treadmill test patient feels like resting. X ray and imaging centres shall fulfil the "Atomic Energy Regulatory Board" (AERB) norms
 - (1) Sufficient space. **Yes/No**
 - (2) Sufficient space for patient waiting. **Yes/No.**
 - (3) Sufficient space for patient resuscitation. **Yes/No**
 - (4) X-ray and imaging centre fulfill AERB norms. **Yes/No**

2. Staff. - All tests shall be carried out by qualified technical persons only as follows:-

Name of Test	Carried out by	Yes/No
X-Ray	Radiographer with Clinical Research Associate (CRA) Qualification or Diploma in Medical Radiology Imaging Technology or BSC in imaging Technology Or Degree or Diploma Course approved by AERB or Certificate/Diploma/ Degree course as approved by State Government/ University recognised by UGC.	
Ultra Sonogram	By a qualified Doctor or by a Radiologist or Concerned Specialist as per the provisions of the Pre-Conception And Pre-Natal Diagnostic Techniques (Prohibition of Gender Selection) Act, 1994	
Electro Cardiogram (ECG)	By an Electro Cardiogram (ECG) Technician trained in Electro Cardiogram (ECG)	
Electroencephalography (EEG)	Electroencephalography (EEG) Technician trained in Electroencephalography (EEG)	
Computed Tomography (CT) scan	By a Radiographer and report by a Radiologist or by the concerned specialist.	
Treadmill	Concerned Technician. A doctor shall be present during the Test.	
Echo Cardiograph	By a Qualified Doctor preferably a Cardiologist By a Qualified Doctor (Post Graduate in field of Radiology, Medicine, Pediatric, Anesthesia, Emergency, Critical care, Clinical Cardiology with adequate experience preferably a Cardiologist (Super Specialist in field of Cardiology)	
Contrast Studies	Radiologist or by the Concerned Specialist	
Magnetic resonance imaging (MRI)	Radiologist or by the Concerned Specialist	

3. Equipments. - Equipments according to the concerned machine. Yes/No

4. Records. - Name, age, gender, address of patient, the nature of investigation done referral doctor, and result of the investigation shall be available in a register. Number of cases treated free of charges shall also be available along with name, age, gender, address and result etc. All the records as mentioned above may be kept electronically and to be linked with the public health record keeping as determined by Govt. authorities from time to time.

Above record maintained as above electronically and/or manually. Yes/No.

I fully understand that in case any of the submitted documents are found to be false or if it is found that I have not fulfilled any of the provisions of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 and the Rules, the Competent Authority shall be at liberty to penalize me / cancel registration as per the provisions of the Act.

Place:

Date:

.....
Signature/Name/Designation/Seal of the Authorized person of the clinical establishment

Signature/Name/Designation/Seal of the Authorized person of inspecting team

(1)
(2)
(3)

By order and in the name of the Governor of Gujarat,

PRAKASH PATNI,
Joint Secretary to Government.

